Message

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Sent: 7/6/2016 2:41:12 PM
To: Ex. 6 Personal Privacy (PP)
Subject: I was quoted in the trade press

IRIS Managers Seek To Strengthen Novel Dermal BaP Cancer Risk Estimate

By Maria Hegstad
Inside EPA
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Managers of EPA's influential risk analysis program are seeking additional expertise on how to strengthen their draft risk analysis of benzo(a)pyrene (BaP), particularly its novel skin cancer risk estimate, but one expert who has reviewed the draft is suggesting the agency just needs to better support its dose metric rather than change that piece of the analysis.

The most scrutinized aspect of EPA's draft BaP assessment is its first-time attempt at calculating a skin cancer risk estimate. Numerous critics have urged EPA to withdraw the number and first craft guidance on how to calculate such numbers, instead of using an important assessment to develop the process.

The BaP assessment is important not just because the compound is a common environmental contaminant but also because EPA has proposed using it as the index chemical in a relative potency factor approach for polycyclic aromatic hydrocarbons (PAHs) -- ubiquitous environmental contaminants.

Vincent Cogliano, director of EPA's Integrated Risk Information System (IRIS) program, explained in opening remarks at a June 30 stakeholder meeting that "one of the issues that the science advisors gave us the most comments on was the modeling for the dermal slope factor, so those are the issues that we're getting at," he said. "We'd like some discussion before we submit" a final draft through the approval process.

Kathleen Newhouse, EPA's chemical manager for BaP, reiterated the agency's interest in having such an estimate when she spoke at the stakeholder meeting in Arlington, VA. Newhouse referenced EPA's risk assessment guidelines for Superfund site cleanups, which she said "note the lack of dermal toxicity values may significantly underestimate" the risks PAHs in soil pose.

Industry critics, however, have argued that the new draft dermal potency factor is overestimated -- though peer reviewers on EPA's Science Advisory Board panel who met in the spring of 2015 to begin reviewing the draft document did not necessarily consider the conclusion overly strict.

One of the panelists, American Cancer Society Managing Director Kenneth Portier, noted that skin cancer is extremely common, and that removals of small malignant patches of skin are generally not reported to cancer registries. As a result, Portier suggested, EPA's draft BaP potency estimate may not be overly large (*Risk Policy Report*, April 21, 2015).

The science advisors struggled with the recommendations on how to best calculate the dermal cancer risk, noting both its novelty and scientific uncertainties in various approaches. The final report, released last April, suggests that there are multiple dose-metric approaches for beginning to estimate the dose, and little information to guide which method EPA should choose.

"The draft assessment used mass rather than mass/skin area as the dose metric for cancer risk at 'low doses' of BaP. Published dermal slope factors for BaP skin carcinogenesis have used mass and mass/skin area as dose metrics and there do not appear to be any empirical data available to inform a choice between these two dose metrics or another metric," the panel's report states.

"The SAB does not have a specific recommendation as to BaP dose metric, but strongly recommends that in the absence of empirical data the decision be based upon a clearly articulated, logical, scientific structure that includes what is known about the dermal absorption of BaP under both conditions of the bioassays and anticipated human exposures, as well as the mechanism of skin carcinogenesis of BaP. The SAB recommends that cancer risk calculated from the derived [dose slope factor] should use absorbed dose, and not applied dose."

But one of the panelists appeared to walk back this concern in remarks at the stakeholders' meeting. John Kissel, a professor of environmental and occupational health sciences at the University of Washington, served as both a discussant on BaP-related topics during the June 30 meeting, as well as a peer reviewer of the document. Kissel said at the stakeholders meeting that the comment referenced the information EPA had included in the assessment, not what is generally available. "When we said [there was not] adequate information to choose the dose metric, we meant in the document, not" what might be available in the public literature, he said.